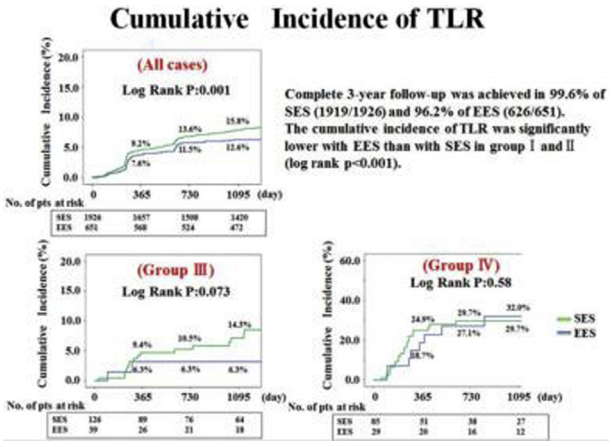
Methods: A total of 1926 patients underwent the first SES implantation between November 2002 and December 2006 and 651 patients underwent the first EES implantation between January 2010 and December 2010, whose target lesion revascularization (TLR) were investigated by telephone follow-up, examining medical records, and asking family physicians. The patients were stratified into 4 groups according to their estimated glomerular filtration rate (eGFR): Group I, eGFR ≥60 ml/min/1.73m2 (normal renal function); Group II, eGFR < 60 and ≥30 ml/min/1.73m2 (mild-moderate RI); Group III, eGFR < 30 ml/min/1.73m2 and not on hemodialysis (HD) (severe RI without HD); and Group IV, renal failure treated with HD (severe RI with HD).
Results: The figure shows the cumulative incidence of TLR at 3 years in all cases and group IV. Complete 3-year follow-up was achieved in 99.6% of SES (1919/1926) and 96.2% of EES (626/651). The cumulative incidence of TLR after EES implantation tended to be lower than that after SES implantation in group I(log rank p< 0.001), II (log rank p< 0.001) and III (log rank p:0.073).



Conclusions: EES might reduce the cumulative incidence of TLR at long term follow up, except for the patients with HD.

TCT-263

Not Early Change in Serum Level Cystatin C, but Baseline Serum Cystatin C Level Predicted Contrast Induced Nephropathy and Cardiovascular Mortality

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Background: Cystatin C has emerged as a sensitive biomarker of renal function. Early change in cystatin C based glomerular filtration rate (CysC-GFR) has been reported to predict contrast induced nephropathy (CIN). We evaluated whether baseline and 24-h change in CysC-GFR after percutaneous cardiovascular intervention using contrast medium (CM) can serve as a prognostic marker of CIN and cardiovascular mortality.
Methods: We evaluated 597 patients who underwent elective coronary (n=357) and peripheral (n=240) intervention from 2010 September to 2013 August at Severance Cardiovascular Hospital, Seoul, Korea. CIN was defined as increase ≥ 25% and/or ≥ 0.5 mg/dl in serum creatinine at 48-h after intervention compared from baseline. Cystatin C and serum creatinine levels were measured before and at 24-h after the procedure. Receiver operating characteristic (ROC) curve with area under the curve (AUC) value were compared for prediction of CIN. Kaplan-Meier survival curve analysis and Cox proportional hazards regression analysis were used to find risk factors of cardiovascular mortality.
Results: Increment of cystatin C level at 24-h from baseline was not able to predict CIN. AUC value of 10, 20, and 30% increment of Cystatin C levels were 0.51, 0.53, and 0.50, respectively. However, baseline CysC-GFR < 60 ml/min showed most superior prediction of CIN (AUC 0.68, 95% Confidence Interval 0.65 – 0.72, P< 0.0001) followed by contrast amount > 200cc (AUC 0.64, P=0.0003), baseline modification of diet in renal disease (MDRD) GFR < 60 ml/min (AUC 0.63, P=0.0005). Although 24-h change in CIN CysC-GFR was not associated with cardiovascular mortality, baseline CysC-GFR < 60 ml/min, baseline MDRD-GFR < 60 min/min, age ≥ 75 years were associated with increased cardiovascular mortality by Kaplan-Meier survival curve analysis. In multivariate Cox regression analysis, only baseline CysC-GFR < 60 was a significant predictor of cardiovascular mortality (hazard ratio 4.1, 95% CI 1.54 – 15.65, P=0.0075).
Conclusions: Baseline CysC-GFR< 60 was a significant predictor of CIN and cardiac mortality after cardiovascular intervention and early change of cystatin C showed no benefit for CIN prediction or cardiac mortality.

TCT-264

Impact of different definitions on prevalence of contrast induced nephropathy in patients undergoing transcatheter aortic valve implantation

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Background: Recently the Valve Academic Research Consortium (VARC) adopted the Akute Kidney Injury (AKIN) system in the place of the Risk, Injury, and Failure, Loss and End-stage kidney disease (RIFLE) system to define akute kidney injury (AKI) following transcatheter aortic valve implantation (TAVI). In this study, we sought to assess differences in prognostic accuracy between the two systems in our real-world retrospective population of patients undergoing TAVI.
Methods: In the present study, 239 consecutive patients undergoing transfemoral TAVI were prospectively enrolled. AKI was defined: (1) according to the AKIN system as a post-procedural creatinine increase of ≥0.3 mg/dl; or (2) according to the RIFLE system as a post-procedural decrease of the creatinine clearance of at least 25%.
Results: Both AKIN and RIFLE system definitions were significantly associated to one-year mortality (binary logistic regression, respectively: (1) OR 3.2, 95%CI 1.5-6.9, p=0.003; and (2) OR 8.5, 95%CI 3.9-18.4, p< 0.001). However, the prognostic accuracy of RIFLE was higher (AUC 0.704; p< 0.001) as with respect to AKIN (AUC 0.602; p=0.037) for the primary end-point of one-year mortality.
Conclusions: In a non-selected patient population undergoing TAVI, the RIFLE system had a higher prognostic accuracy in comparison to the currently proposed AKIN system.

TCT-265

Contrast induced acute kidney injury in patients undergoing transcatheter aortic valve implantation – interaction with left ventricular ejection fraction

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Background: The prognostic relevance of direct contrast toxicity in patients undergoing transcatheter aortic valve implantation (TAVI) remains unclear, due to the confounding hemodynamic effect of acute left ventricular ejection fraction (LVEF) impairment on kidney function estimation.
Methods: In the present study, 239 consecutive patients undergoing transfemoral TAVI were prospectively enrolled. Contrast induced acute kidney injury (CI-AKI) was defined according to the VARC-2 criteria as a post-procedural creatinine increase of ≥0.3 mg/dl.
Results: While LVEF and creatinine values at admission were not significantly associated to CI-AKI, their interaction term significantly defined CI-AKI (p=0.033). The long-term survival (1.7±1.4 years) was significantly lower in the CI-AKI patient group (log-rank=5.1, p=0.025). In the Cox-regression multivariate model analysis CI-AKI was an independent predictor of mortality (HR 2.2, 95%CI 1.1-4.7, p=0.034), along with LVEF (HR 0.97, 95%CI 0.95-0.99, p=0.012).
Conclusions: In a non-selected patient population undergoing TAVI, CI-AKI was confirmed as an independent predictor of clinical outcome. Interestingly, only the interaction between LVEF and baseline creatinine values was found to determine CI-AKI.

Drug-Eluting Balloons and Local Drug Delivery

Washington Convention Center, Lower Level, Hall A

Saturday, September 13, 2014, 5:00 PM–7:00 PM

Abstract nos: 266-289

TCT-266

PEPCAD-DES: A randomized, multicenter, single blinded trial comparing paclitaxel coated balloon angioplasty with plain balloon angioplasty in drug-eluting-stent restenosis – 3 year results

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Background: We evaluated the impact of paclitaxel-coated balloon angioplasty for treatment of drug-eluting stent restenosis compared with uncoated balloon angioplasty alone.
Methods: In this prospective, single-blind, multicenter, trial we randomly assigned 110 patients with Instent-Restnosis of drug eluting stents to undergo treatment either with paclitaxel coated balloon (SeQuent Please, BBraun, Melsungen) or balloon angioplasty alone. Primary endpoint was in-stent late lumen loss at 6 months. Secondary

clinical endpoint was composited of cardiac death, myocardial infarction attributed to the target vessel or TLR.
Results: There was no difference in patient baseline characteristics. Lesion length was 11.2±6.5mm in the DCB- and 12.2±8.2mm in the POBA-group (p=n.s). Post PCI, for the stented segment and the total segment minimal lumen diameter and diameter stenosis were not different. Clinical follow-up after 12 months was 100%. Treatment with DCB was superior to balloon angioplasty alone with an in-stent late loss of 0.43±0.61mm vs. 1.03±0.77mm (p< 0.001). Minimal lumen diameter was significantly larger and percent diameter stenosis significantly lower with use of the DCB for both the stented and total segment. Restenosis rate was reduced from 58.1% to 17.2% (P< 0.001) and the clinical endpoint at 6 months was reduced from 50% to 16.7% (P< 0.001), respectively. After 12 months the effect of DCB persisted (clinical endpoint 52.6% vs. 16.7%; p< 0.001 and TLR 36.8% vs. 15.3%, p=0.005), respectively. There was one probable stent thrombosis in the POBA group. Clinical follow-up after 3 years will be completed in June 2014 and presented.
Conclusions: Paclitaxel coated balloon angioplasty was superior to balloon angioplasty alone for the treatment of instent-restenosis of drug-eluting stents. Longterm effects of the DCB-therapy after 3 years will be presented.

TCT-267

Lower Mortality of Paclitaxel-Coated Balloon Compared with Paclitaxel-Eluting Stent for the Treatment of DES In-Stent Restenosis: Two-Year Follow-Up of the PEPCAD China ISR Trial

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Background: Previous studies demonstrated that angioplasty with a paclitaxel-coated balloon (PCB) was non-inferior to paclitaxel-eluting stent (PES) implantation when used to treat drug-eluting stent in-stent restenosis (DES-ISR). There is a paucity of data regarding the long-term safety and efficacy of using PCB in treating DES-ISR. We sought to present for the first time the 2-year clinical outcomes from PEPCAD China ISR trial.
Methods: PEPCAD China ISR was a 220 patient randomized (1:1), single blind prospective multicenter trial conducted in China. Patients with DES-ISR received either PCB (SeQuent® Please, B.Braun Melsungen AG, Germany) or PES (Taxus® Liberté, Boston Scientific, Natick, MA, USA) treatment. The primary endpoint was in-segment late lumen loss (LLL) at 9 months. Secondary endpoints included 9-month % diameter stenosis (DS), binary restenosis rate, and 1- and 2-year target lesion failure (TLF) defined as the composite of cardiac death, target vessel myocardial infarction or ischemia-driven target lesion revascularization. In addition, definite/probable stent thrombosis (ST) rates were documented.
Results: At 9 months, the in-segment LLL, %DS and binary restenosis were not significantly different between PCB and PES group (0.46±0.51mm vs. 0.55±0.61mm; 29.0 ± 21.3 vs. 30.8 ± 25.3; 18.6% vs. 23.8%; p>0.05 respectively). No adverse ischemic events occurred between 1 to 2 years in PCB group except 1 non-target vessel revascularization. However, the rate of all-cause death was statistically lower in the PCB group (0% vs. 4.9%, p=0.03) compared with PES group at 2 years. Major results are shown in the table.

Table. Clinical Outcomes through 2 Years

	12 Months			24 Months		
	PCB, n=109	PES, n=106	p	PCB, n=107	PES, n=102	p
Death, % (n)	0 (0)	1.9 (2)	0.24	0 (0)	4.9 (5)	0.03
Cardiac Death, % (n)	0 (0)	0 (0)	-	0 (0)	2.0 (2)	0.24
Myocardial Infarction, % (n)	3.7 (4)	6.6 (7)	0.33	3.7 (4)	6.9 (7)	0.31
Q Wave MI, % (n)	0 (0)	0.9 (1)	0.49	0 (0)	1.0 (1)	0.49
Target Vessel MI, % (n)	2.8 (3)	6.6 (7)	0.21	2.8 (3)	6.9 (7)	0.21
Ischemia-Driven TLR, % (n)	14.7 (16)	10.4 (11)	0.34	15.0 (16)	11.8 (12)	0.5
TLR, % (n)	15.6 (17)	12.3 (13)	0.48	15.9 (17)	13.7 (14)	0.66
TVR, % (n)	16.5 (18)	16.0 (17)	0.92	16.8 (18)	17.7 (18)	0.87
Any Revascularization, % (n)	22.0 (24)	17.9 (19)	0.45	23.4 (25)	20.6 (21)	0.63
TLF, % (n)	16.5 (18)	16.0 (17)	0.92	16.8 (18)	18.6 (19)	0.73
PoCE (composite of all cause death, all MI, and any revascularization), % (n)	23.9 (26)	23.6 (25)	0.96	25.2 (27)	30.4 (31)	0.41
Definite or Probable Stent Thrombosis, % (n)	0.9 (1)	0.9 (1)	1.00	0.9 (1)	1.0 (1)	1.00

Conclusions: The prolonged 2-year clinical follow-up showed that there was no newly occurred death, MI, TVR, or ST in PCB group between 1 and 2 years, and statistically, a lower all-cause mortality of PCB compared to PES for the treatment of DES-ISR. (ClinicalTrials.gov identifier: NCT 01622075)

TCT-268

Randomized clinical trial favors the use of drug-coated balloons over plain balloons for the postdilatation of nitinol stents in the SFA and PI segment to lower restenosis rate

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Background: Stents are needed in up to 50 % of all peripheral interventions where PTA with plain or drug-coated balloons alone will not reopen the vessel sufficiently. Nevertheless, the restenosis rate of stents is still a major limitation of peripheral arterial interventions. Drug-coated balloons potentially overcome the problem of in-stent restenosis when used for postdilatation after primary nitinol stenting in the SFA and PI segment.
Methods: The Freeway Stent Study is a prospective, randomized, international trial started in 15 centers in Germany and Austria. 200 patients will be enrolled and randomized equally to primary nitinol stenting followed by either DCB (Freeway™) or plain balloon postdilatation. Primary endpoint is clinically driven target lesion revascularization (TLR) at 6 months, secondary endpoints include further clinical and safety evaluations like shift in Rutherford classification and ABI, LLL, patency rate and MAE.
Results: Over 170 patients have been enrolled to date, of which 130 have finished the 6 months and almost 100 the 12 months follow-up. The results highly favor the use of Freeway™ DCB over plain balloon based on clinically driven TLR (only 3.2 % vs. 10.2 % at 6 months and 8.0 % vs. 17.4 % at 12 months). This is supported by a statistically significant better clinical outcome for PAD patients treated with DCB as postdilatation device regarding primary patency rate, ABI and Rutherford classification at six months.
Conclusions: The use of DCB as postdilatation device is investigated in a new approach to decrease the restenosis rate after nitinol stenting in the SFA and PI segment. The latest interim results of the Freeway Stent Study show that DCB might significantly lower the in-stent restenosis rate in the treatment of PAD patients.

TCT-269

Drug-coated balloon vs. standard balloon for the PTA treatment of lesions in the SFA and popliteal artery – First interim results of the FREERIDE study

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Background: Drug coated balloons (DCB) have provided a new option in the treatment of peripheral artery disease, because they allow elution of an anti-proliferative agent into the vessel wall. With the standard methods like the plain old balloon angioplasty (POBA) the effort to restore the normal flow often fails due to restenosis. The FREERIDE study investigates the inhibition of restenosis by the (Paclitaxel) DCB Freeway (Eurocor GmbH, Bonn, Germany) versus standard balloon PTA, in the treatment of de-novo occluded, stenotic or reoccluded lesions in peripheral arteries (SFA and popliteal artery/PI segment).
Methods: Controlled multicenter trial conducted in 23 centers worldwide with 280 PAD patients randomized either to Freeway DCB or to POBA. The primary endpoint is the rate of target lesion revascularization (TLR) at 6 months. Further, several secondary endpoints like late lumen loss and patency rate at 6 months, TLR at 12, 24 months follow up (FU), change in the Ankle-brachial index (ABI) and Rutherford classification at FU, and MAE are investigated.
Results: Until the date 84 patients have been enrolled, 62 completed the 6 months FU, 8 have not been available for FU. The interim results show that there was remarkably more bail out stenting after POBA compared with Freeway PTA (8.9% vs. 25.6%; p=0.04). After 6 months there were clear positive trends in the TLR rate for the Freeway arm (5.4% vs. 20%; p=0.07). MAE were significant lower in the Freeway arm compared to POBA (5.4% vs. 28%; p=0.01) with 0% vs. 8% death, 0 % both arms for study related amputation and thrombosis. Furthermore there were promising clinical outcomes in Rutherford classification after Freeway vs. POBA.
Conclusions: The interim results indicate that the (Paclitaxel)-coated balloon Freeway might provide an advantage for PTA in SFA lesions and PI segment. The drug coated balloons could result in better outcomes overcoming the existing limitations in peripheral artery disease treatment.